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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,552	12/05/2003	Mark E. Deem	514362000204	4326

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^{07/29/2009}

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

07/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/729,552

Applicant(s)

DEEM ET AL.

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 31-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 31-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 08/11/2008.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-12 and 31-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gambale** (U.S. Pub. No. **2003/0208209**).

Claims 1-2, 7, 10-12, 31-32, 37, and 40-42: Gambale discloses a tissue positioning device **868** having a first opening or port **860** in a first region for releasably adhering a first area of tissue and a second opening or port **860** for releasably adhering a second area of tissue thereto, the first and second openings being separated by a septum **852** at least one fastener **880, 878** housed within the device at least one fastener to be deployed such that the first area of tissue is secured to the second area of tissue via the fastener (Figures 40-42).

Gambale discloses the claimed device except for the septum being removable from between the first and second openings and adapted for abrading adjacent tissue.

Gambale teaches methods of abrading adjacent tissue selected from the group consisting of cutting, scoring, heating, freezing, and chemical ablation on the septum (page 3, paragraphs 24-27), but does not expressly disclose a *removable* septum

adapted to abrade adjacent tissues. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a removable septum that provides the methods of abrading adjacent tissue as disclosed by Gambale, in order to selectively abrade the tissue (using mechanical means **884** in Figure 41, for instance) resulting in the initiation of a healing process on the tissue surfaces and also to facilitate separation of the tissue from the tissue positioning device. It has also been held that constructing a formerly integral structure in various separable, removable elements involves only routine skill in the art, and therefore it would have been an obvious modification to make the septum removable.

Claims 3 and 33: Gambale discloses the tissue positioning device defining a plurality of additional regions for adhering additional tissue thereto (Figures 36-37).

Claims 4 and 34: Gambale discloses the first region and the second region being adjacently located (Figures 40-42).

Claims 5 and 35: Gambale discloses the first area of tissue and the second area of tissue being adhered to the tissue positioning device via a vacuum created in the first region and the second region (pages 16-17, paragraph 171).

Claims 6, 8-9, 36, 38-39: Gambale discloses the first region and the second region being in fluid communication with a common channel **894** defined within the tissue positioning device (Figures 40-42), as well as a plurality of additional fasteners **878, 874** housed within the device which may comprise staples (page 4, paragraph 28).

Response to Arguments

3. Applicant's arguments filed 08/11/2008 have been fully considered but they are not persuasive.
4. Applicant argues that it is unobvious from the teachings of Gambale to modify the septum **852** of the device to be removable without reconstructing the entire device, and since a single unit, as opposed to a multi-piece unit that would result from a removable septum, has advantages in Gambale over the prior art. Since Gambale teaches multiple configurations for the septum with different abrasion means, such as mechanical abrasion means **884** in Figure 41, and radio frequency abrasion means **888** in Figure 42, it may occur to one of ordinary skill in the art to make the septum removable in order to allow the user to change the abrasion means of the septum before applying the device to tissue, depending on the desired configuration. Also, as mentioned above, it may be beneficial to have a removable septum to selectively abrade the tissue (using mechanical means **884** in Figure 41, for instance) resulting in the initiation of a healing process on the tissue surfaces and also to facilitate separation of the tissue from the tissue positioning device. It has also been held that constructing a formerly integral structure in various separable, removable elements involves only routine skill in the art, and therefore it would have been an obvious modification to make the septum removable. The teaching of Gambale having an advantageous single unit is not considered to teach away from a multi-piece unit, and therefore does not render the modification unobvious.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734